REMARKS

35 U.S.C. § 101 Claim Rejections

Claims 1, 46, and 48-50 are rejected under 35 U.S.C. § 101 because the claimed invention is allegedly not supported by a specific, substantial and credible asserted utility or a well established utility.

The Board has issued a new ground of rejection in this case based on an alleged lack of utility. Applicants respectfully traverse this rejection since proteins like AKT1 (and the biochemical pathways that they are associated with), were known at the time of filing, and disclosed in the specification as drug targets. In essence, the Board's rejection is based on the allegation that specification does not provide any evidence of specific association of the claimed complexes with any disorder. The Board alleges that "In sum, the specification provides no information about the specific physiological pathway or disorder which is associated with the protein complex." The Board dismisses Applicants' assertion of utility as being to nebulous and non-specific to meet the utility requirement. The Board also alleges that the specification provides no evidence of association of the complexes with cell proliferation and apoptosis. Since these proteins and/or associated biochemical pathways are targets for drug development, the protein complexes can be used to screen for modulators of that protein, the protein complex and/or the interacting partner. Applicants therefore respectfully request withdrawal of this rejection.

An inquiry by the Patent Office into whether a claimed invention satisfies the utility requirement typically has two distinct prongs. First, the Patent Office must determine whether the patent applicant has asserted a specific and substantial utility for the claimed invention *In re Fisher*, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005). Second, the Patent Office must ascertain whether there is any evidence that one of ordinary skill in the art would reasonably doubt the invention's asserted utility. *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). The PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal

evidence sufficient to convince such a person of the invention's asserted utility. *See In re Bundy*, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981).

PTO has not provided adequate evidence to establish a *prima facie* case to doubt the assertion in the specification that the protein complex between AKT1 or AKT2 and FNTA, TRPD, KIAA0728, PPL, Golgin-84, CLIC1, and AKR7A2 are useful for screening for modulators of AKT1 or AKT2, which are associated with physiological pathways and disorders, one particular pathway asserted being apoptosis.

The PTO did not take the first and necessary step to present facts that would establish that the asserted utility would be reasonably doubted by one of ordinary skill in the art. To the contrary, the PTO merely alleges "No evidence is provided in the specification to associate the claimed complexes with any specific physiological pathway or function." Applicants have disclosed what they assert is a physiologically relevant set of protein-protein interactions as evidenced in the literature by the fact that some of the claimed proteins complexes are associated with the same or similar biochemical pathways in the literature, the yeast two-hybrid system used to identify the protein interactions is very robust and well controlled to eliminate false positives, the network of proteins provide additional confirmatory evidence of the association of these complexes with specific pathways. These proteins and their associated biochemical pathways were disclosed in the specification as being therapeutic targets.

Applicants direct the Examiner's attention to paragraph [0019] of the specification which discloses that AKT1 and AKT2 are involved in control of cell proliferation and apoptosis. This disclosure is supported by numerous references cited in paragraph [0019] and supported by the fact the AKT pathway is a major therapeutic target for cancer and other diseases. Examiner is particularly directed to the Ozes et al. reference (of record) which teaches that Akt1 is involved in the activation of NFkB, which in turn regulates the inhibition of apoptosis. AKT is involved in the specific physiological apoptotic pathway and has presently been found to be involved in protein-protein interactions, the protein complexes of which, are useful to screen for modulators of AKT1/AKT2. Thus, AKT1/AKT2 are specifically involved in the apoptotic pathway

and are part of a broader network of interacting proteins as confirmed by Applicants' specification..

An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement. *Raytheon v. Roper*, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984). Because of the role of AKT in regulating apoptosis and AKT's involvement in cancer (and other diseases as disclosed in the specification), Applicants asserted in the as-filed specification that protein-protein interactions with AKT are useful to screen for therapeutics. This assertion is further supported by literature available to those of skill in the art upon filing demonstrating that both AKT and at least one of the proteins described within the specification are involved in apoptosis.

For instance, Kun Jiang et al. (herein submitted as Exhibit A) teaches that farnesylated proteins are involved in the activation of AKT2, and that a farnesyl transferase inhibitor preferentially induces apoptosis in AKT2-overexpressing cancer cells. Farnesyl transferase inhibitors play an active role in modulating apoptosis, strongly implicating a role for the claimed FNTA (farnesyl transferase) protein's involvement in the apoptotic pathway as well. Since both FNTA and AKT2 are both known to play important roles in the physiological pathway of apoptosis, one of ordinary skill in the art would reasonably conclude that the presently discovered protein-protein complex claimed between FNTA and AKT2 would indeed provide a presently available utility for an effective method of screening for modulators of the complex to affect the apoptotic pathway.

Additionally, Mitsuuchi et al. (of record) teaches AKT1 and AKT2 activity are both implicated in response to marketed cancer therapeutics (cisplatin and paclitaxel). Thus, the literature clearly implicates AKT1 and AKT2 activity to pathways related to regulating apoptosis which is specifically related to cancer.

Other evidence cited in the record supports the involvement of these proteins in disease pathways – the mere use of broad language in the specification such as "associated with mammalian physiological pathways", "physiological disorders", and

"biological activity" cannot lead to a conclusion of lack of utility as the Board is urging. The broad language simply indicates, as the skilled artisan at the time of time of filing was fully aware, that the proteins are involved in a broad array of disorders. The broad array of disorders is associated with common biochemical and physiological pathways. The record clearly indicates that proteins like the AKT's are involved in specific diseases.

Substantial evidence of record indicates that the disclosed protein complexes have utility. The baits chosen to discover the novel interactors disclosed herein were chosen for their known involvement in a disease related pathway, in this case apoptosis, neurodegeneration and cancer. The specification relates that AKT kinases are involved in cell survival, insulin regulated glucose transport, and the development of non-insulin dependent diabetes mellitus at paragraph [0019], which are established therapeutic targets. The PTO has previously admitted on record that there is little doubt that these protein complexes will be found to have patentable utility – indicating that it is more likely than not that complexes have utility. The PTO has not provided any evidence to call into question Applicants' presumptively correct assertion of utility. In view of the evidence of record indicating a substantial specific and credible utility for the protein complexes under examination, Applicants respectfully request withdrawal of this rejection.

35 U.S.C. § 112 Claim Rejections

Claims 1, 46 and 48-50 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to adequately teach how to use the instant invention. Since Applicants have disclosed a specific, substantial and credible utility, as discussed above, this rejection is rendered moot. Applicants therefore respectfully request withdrawal of this rejection.

CONCLUSION

Claims 1, 46, and 48-50 are believed to be in condition for allowance, and a notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned agent. It is not believed that any fees are required with this response. If this is incorrect, the Commissioner is hereby authorized to charge any appropriate fees or deficiency or credit any overpayment to Deposit Account no. **50-1627**.

Respectfully submitted,

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